REMARKS

In the present Reply, no claims are being added, canceled or amended. Thus, a listing of the claims is not necessary. Claims 2-13, 17-19 and 22-40 are currently pending in the application. Claims 2-13, 17-19 and 22-40 stand rejected.

In view of the following remarks, Applicant respectfully requests that the Examiner withdraw all rejections and allow the currently pending claims.

Priority

Applicant notes that the Examiner has not acknowledged Applicant's claim for priority in the Office Action of November 30, 2005 and several preceding Office Actions, as is duly recorded by the USPTO and immediately apparent from the Official Filing Receipt of March 23, 2001, page 1. The Examiner is requested to acknowledge the priority claim in the next response, and to acknowledge receipt of the priority documents from the International Bureau (IB). If the Examiner is experiencing difficulty in obtaining the priority documents, the Examiner is invited to contact Applicant's representative.

Information Disclosure Statement

The Examiner states that the Information Disclosure Statement (IDS) filed February 17, 2005 failed to comply with the requirements of Rule 98. The Examiner specifically states that Applicant failed to provide an English translation, as stated in the IDS. First, Applicant directs the Examiner's attention to page 2 of the IDS wherein it is stated "WO 97/46246 corresponds to EP 0814 138 B1. An English translation of the claims of EP '138 are attached. A Family List

for WO '246 is also attached." Second, the Examiner has signed off on WO'246, as indicated in the returned, signed Form PTO-1449. WO '246 provides an English language abstract on its front page. Thus, the subject matter of EP '138 has been considered by the Examiner. (*See*, EP '138, front page, top right corner, wherein it is indicated that the EP application is related to WO '246). Third, as evident from the PAIR entry of February 17, 2005, the English translation of the claims of EP '138 were received and scanned by the USPTO. (*See*, entry of February 17, 2005, corresponding to EP '138, at pages 5-8).

It is respectfully submitted that the claims present in English of the EP '138 reference and the corresponding WO '246 disclosure accurately reflect the relevance of EP '138. Thus, the Examiner is requested to return a fully signed copy of the Form PTO-1449 indicating consideration of EP '138.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claim 40 stands rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. (*See*, Office Action of November 30, 2005, at page 3, hereinafter, "Office Action"). Applicant traverses the rejection as set forth herein.

The Examiner states that although the instant specification is enabling for "treating skin irritations, sun burn, cellulites, wrinkles, acne, neurodermatitis, ozone damage, burns, caustic burns, thickening, edemas, hematomas, hemorrhoids," it does not reasonably enable treating "herpes, rheumatism, arthrosis, and skin cancer." (*Id.*). The Examiner further states that although Applicant's arguments have been considered, the rejection will be maintained "until Applicant submits the article that the arguments are based on," referring to the Watzl et al.

reference. Attached hereto for your consideration, marked as Exhibit A, is a copy of the Watzl et al. reference.

Reconsideration and withdrawal of the enablement rejection of claim 40 are respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Claims 2, 5-11, 17-19 and 26-40 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Murad, U.S. Patent No. 5,962,517 (hereinafter, "Murad"), in view of Oliver, U.S. Patent No. 5,869,062 (hereinafter, "Oliver"). (*See*, Office Action, at page 6). Applicant traverses the rejection as hereinafter set forth.

M.P.E.P. § 706.02(j) sets forth the standard for establishing a *prima facie* case of obviousness as follows:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Although Murad was allowed on October 5, 1999, it may qualify as prior art under 35 U.S.C. § 102(e) because Murad claims priority back to the filing date of its related provisional application (U.S. Patent Application Serial No. 60/036,825) which was filed on January 31, 1997. Thus, the basis for availability of Murad under 35 U.S.C. § 103(a) is its qualification

under 35 U.S.C. § 102(e). Prior art available under 35 U.S.C. § 102(e)/103(a) may be antedated through Declaration under 37 C.F.R. § 1.131. (*See*, MPEP § 706.02(k)(D)). Therefore, attached hereto is a Declaration under 37 C.F.R. § 1.131 wherein the present Inventor attests to the fact that the present invention was completed "already mid-year 1996." Thus, Murad is antedated and is no longer available as prior art under 35 U.S.C. § 102(e) and/or 35 U.S.C. § 103(a).

Furthermore, Oliver was allowed on February 9, 1999, but claims priority to its filing date of May 27, 1997. Thus, Oliver may qualify as prior art under 35 U.S.C. § 102(e) as of its filing date of May 27, 1997. Again, the present Inventor submits herewith the Declaration under 37 C.F.R. § 1.131. This Declaration antedates Oliver as well because the inventor attests to the fact that the present invention was completed "already mid-year 1996." Thus, Oliver is antedated and is no longer available as prior art under 35 U.S.C. § 102(e) and/or 35 U.S.C. § 103(a).

Even considering the disclosures of the references, they do not, either individually or in combination, disclose or suggest each and every element of the presently claimed invention. Thus, a *prima facie* case of obviousness has not been established, for the following reasons.

Murad discloses a pharmaceutical composition for treating acne and conditioning the skin cells. However, Murad does not disclose or suggest explicitly the use of any zinc oxide. Although the disclosure of Murad points to the use of zinc components, Murad strongly suggests that the preferred embodiment uses a zinc complex with ascorbic acid or ascorbate. (*See*, Murad, at column 5, lines 44-49, and Examples). Furthermore, inspection of the Examples reveals that Murad discloses formulations provided in capsule and tablet form. Murad is silent with respect to any inorganic peroxide. That is, there is no disclosure in Murad pointing to any formulation

for topical application comprising, in part, a combination of zinc oxide and an inorganic peroxide. Therefore, Murad fails to disclose or suggest each and every element of the presently claimed invention.

Oliver discloses a skin treatment composition comprising calamine which is zinc oxide in combination with ferric oxide. The composition of Oliver further includes other components such as vitamins and naturally occurring antibacterial products. Oliver also discloses using peroxide as an "optional" component. Oliver does not disclose or suggest a composition comprising an alkali or alkaline earth salt, an amino acid and a secondary plant substance as recited in the present claims. Thus, Oliver also does not disclose or suggest each and every element of the presently claimed invention.

Furthermore, there is no motivation, found either within the references themselves or within the knowledge of one of ordinary skill in the art, to combine both references and to pick and chose among the various parts of the disclosure to arrive at the specific formulations recited by the presently claimed invention. The goal of Oliver is to provide a skin treatment composition that only incorporates natural ingredients. (*See*, Oliver, at column 2, first paragraph). Thus, Oliver provides a skin treatment composition that clears up most skin-related problems naturally. (*Id.* at column 1, first paragraph). Oliver discloses at column 3, lines 49-51 that one of the advantages of the treatment composition is that it will not cause any side effects when used. This is because only natural ingredients are used. Furthermore, Oliver only discloses a formulation for topical application. Contrary thereto, Murad discloses mainly a formulation for oral administration. (*See*, Murad, at column 9, line 52, and Examples). Additionally, the compositions disclosed by Murad comprise many non-natural ingredients that

clearly teaches away from the disclosure of Oliver. One of ordinary skill in the art would not combine these two disclosures because one is directed at excluding non-natural ingredients and the other explicitly directs use of non-natural ingredients. Thus, the two disclosures are inconsistent in application and direction.

Reconsideration and withdrawal of the obviousness rejection of claims 2, 5-11, 17-19 and 26-40 are respectfully requested.

Murad & Oliver & Horrobin et al. (U.S. Patent No. 5,145,686)

Claims 3, 4, 13 and 22-25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Murad, in view of Oliver in further view of Horrobin et al., U.S. Patent No. 5,145,686 (hereinafter, "Horrobin et al."). (*See*, Office Action, at page 10). Applicant traverses the rejection as hereinafter set forth.

The disclosures of Murad and Oliver have already been addressed, above, with respect to the obviousness rejections of claims 2, 5-11, 17-19 and 26-40. Horrobin et al. disclose a pharmaceutical composition for topical application comprising at least one lithium salt and approximately 3 wt. % of evening primrose oil. At column 1, line 63 and column 3, lines 57-59, Horrobin et al. disclose that lysine is an option ingredient. However, Horrobin et al. do not point in a general way to any amino acid. Furthermore, Horrobin et al. neither disclose nor suggest the use of zinc oxide. The disclosure of Horrobin et al. is silent with respect to any combination of zinc oxide and an inorganic peroxide nor to a combination of these components with at least one amino acid, nor is there any disclosure pointing to any effects of such combinations.

Therefore, the Examiner has not established a *prima facie* case of obviousness with respect to the presently claimed invention in light of the cited references because Horrobin et al., alone, or in combination with the disclosures of Oliver and Murad, do not disclose or suggest each and every element of the presently claimed invention.

Furthermore, there is no motivation from within the references themselves or from the knowledge of one of ordinary skill in the art to suggest combination of these references, as already discussed, above.

Reconsideration and withdrawal of the obviousness rejection of claims 3, 4, 13 and 22-25 are respectfully requested.

Murad & Oliver & Horrobin et al. & Burke et al. (U.S. Patent No. 5,693,318)

Claim 12 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Murad, in view of Oliver, in further view of Horrobin et al., and in further view of Burke et al., U.S. Patent No. 5,693,318 (hereinafter, "Burke et al."). (*See*, Office Action, at page 11). Applicant traverses the rejection as hereinafter set forth.

The disclosures of Murad, Oliver and Horrobin et al. have already been addressed, above, with respect to the obviousness rejections of claims 2-11, 13, 17-19 and 22-40. Now turning to Burke et al., Applicant interprets Burke et al. to disclose an aqueous skin care composition comprising peroxides, salicylic acid, a surfactant and a specific phosphate ester. The disclosure of Burke et al. describes the use of phosphate esters to facilitate the formulation of an aqueous-based skin cleanser that is compatible with and stabilizes peroxide and salicylic acid. (*See*, Burke et al., at column 2, third paragraph). However, Burke et al. is silent with respect to any

composition comprising at least one amino acid and at lest one secondary plant substance, as presently claimed. Furthermore, Burke et al. are silent with respect to any treatment of skin diseases and the like. Since the disclosure of Burke et al. are specifically directed at an aqueous cleanser, a person of ordinary skill in the art would not use this reference for solving the object of the presently claimed invention.

Furthermore, one of ordinary skill in the art would not be motivated to combine the references of Burke et al. and Horrobin et al., since no motivation to do so is found within the references and because the disclosure of Burke et al. is directed to an aqueous skin cleanser and to addressing the problem of formulating peroxide and salicylic acid-containing compositions. The disclosure of Burke et al. is focused on the finding that the use of phosphate esters facilitate the formulation of an aqueous-based skin cleanser comprising peroxide and salicylic acid and stabilizing peroxides. (*See*, Burke et al., at column 1, penultimate paragraph and column 2, third paragraph). This is different from the aim and object of the disclosure of Horrobin et al., which is also different than the problem(s) to which the disclosures of Murad and Oliver are directed.

Reconsideration and withdrawal of the obviousness rejection of claim 12 are respectfully requested.

Finally, in a further rebuttal to any possible case of *prima facie* obviousness the Examiner may be able to make based on the foregoing references, Applicant submits herewith a Declaration under Rule 132 detailing comparative tests encompassing the presently claimed invention. The comparative Examples were performed under the direct supervision of the Inventor and were performed as instructed by the present Inventor. The comparative data

disclosed in the Declaration show that a formulation comprising both zinc oxide and inorganic peroxide (formulation R3) provides an unexpectedly superior result over formulations containing only ZnO or inorganic peroxide (formulations R1 and D2, respectively).

The Inventor further points out that effects of formulations such as additive effects are generally not predictable in the present field. The Inventor indicates that the question of combined effects of two different formulations can only be clarified in extensive experimental test series. The Inventor emphasizes that only by such empirical tests may one determine whether the effect of a known recipe increases or is maintained or decreases if a further ingredient or drug is added. Starting from the cited references, or the formulations R1 and R2, the significant improvement of the effects of formulation R3 is not obvious considering the addition of these additives alone. That is, combination of two different formulations in theory does not allow any conclusion an whether the new formulation has any desired effect at all. Particularly, it does not allow any conclusion as to whether such a pharmaceutical composition has any improved effects. These facts can only be obtained through extensive testing. Therefore, the improving effects of formulation R3 are neither obvious nor able to be predicted with any degree of success from the disclosures of any of the cited references, either individually, or in combination.

CONCLUSION

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Thomas J. Siepmann, Ph.D. (Reg. No. 57,374) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Dated: May 26, 2006

Respectfully submitted,

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